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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,910	04/07/2000	Yadong Huang	06510/12IUS1	2429

7590 12/11/2001

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EXAMINER
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RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/11/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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09/544,910

EXAMINER
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ART UNIT	PAPER
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15

DATE MAILED:

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**Commissioner of Patents and Trademarks**

**Advisory Action**

Application No.

09/544,910

Applicant(s)

HUANG ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 November 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-11.Claim(s) withdrawn from consideration: 12-35.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See Continuation Sheet

+ Interview Summary

Continuation of 10. Other: Note the attached Interview Summary (Paper No. 14). Furthermore, the proposed amendments will not be entered for the reason set forth in the note of explanation, which is attached..

### NOTE OF EXPLANATION

1. The proposed amendment will not be entered because they raise new issues that would require further consideration and/or search and which furthermore are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

The proposed amendment to claims 1 and 5 raise new issues with regard to the requirement of 35 USC § 112, second paragraph that claims particularly point out and distinctly claim the subject matter of that Applicants regard as the invention. The proposed amendment to claims 1 and 5 to recite the limitation "by reducing the expression of apoE" would render the indefinite because it is unclear that the specification provides a standard for ascertaining the requisite degree to which the expression of apoE must reduced to at least reduce the amount of plasma active apoE in the host. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Because the proposed amendment to claims 1 and 5 would raise new issues, the amendment will not be entered.

Furthermore, in an apparent attempt to distinguish the prior art from the claimed invention, the amendment to claims 1 and 5 narrows the scope of the claims to an agent that reduces the amount of plasma active apoE by reducing the expression of apoE. In this regard, the amendment would require further consideration and any further consideration would require a new search, constituting another reason that the amendment will not be entered. At any rate, as stated in the previous Office Action, contrary to Applicants' assertion, the molecular mechanism by which gemfibrozil, for example, exerts its pharmacological effects is not fully understood. Moreover, the claims are still drawn to an undisclosed agent and therefore it is clearly unreasonable to assert that the mechanism by which the undisclosed agent reduces the amount of plasma active apoE and mechanism by which the agents of the prior art reduce the amount of plasma active apoE are different. Nevertheless, upon consideration of Applicants' remarks, it is evident that Applicants are contemplating the use of antisense

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nucleic acids to inhibit the expression of apoE, but again the claims are not limited to antisense nucleic acid molecules. Besides, the Office has made a *prima facie* case for lack of enablement with regard to claims drawn to an invention wherein antisense nucleic acid molecules are used in Paper No. 9, which has not been resolved.

In summary, in addition to raising new issues, which would require further consideration and further search, the proposed amendment would not place the application in better form for appeal. Furthermore, Applicants' remarks have been fully and carefully considered, but not found persuasive. Therefore, the proposed amendment will not be entered.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

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December 6, 2001

  
DONNA WORTMAN  
PRIMAR EXAMINER